

REMARKS UNDER 37 CFR § 1.111

Formal Matters

Claims 1, 5-22, 25-33, 40-54, 58-91, 97, 100-107, 225, 229-255, 282 and 284-300 are pending after entry of the amendments set forth herein.

Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were examined. Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

The Office Action

Claims Rejected Under 35 U.S.C. Section 112, First Paragraph

In the Official Action of March 7, 2007, claims 107-94 were rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserted that the claims contain subject matter that was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The language at issue was identified as “wherein said energy delivery portion is locatable at any position within said distal end portion to delivery ablative energy through said any position”.

Applicants respectfully traverse this ground of rejection. It is respectfully submitted that one of ordinary skill in the art, upon reading the present specification and reviewing the present drawings, would understand that the energy delivery portion can be positioned at any location along the distal end portion to deliver ablative energy. For example, Figs. 1A, 1B and 13A-13D and descriptions thereof show and describe that the energy delivery portion 27 is slidable within sheath 22. Further, since the contact surface 23 of the catheter is transparent to the ablative energy, predefined openings in the catheter are not required for delivery of ablative energy and thus ablative energy can be delivered

through the contact surface at any location along the distal end portion. Accordingly, it is respectfully submitted that this ground of rejection is improper and should be withdrawn. Applicants do not acquiesce to this ground of rejection, but have canceled the claim language at issue in order to advance the prosecution of the instant application.

Applicants further respectfully submit that claim 94 was previously canceled, and therefore it is respectfully submitted that the current rejection of claim 94 is improper.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 107-94 under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement, as being moot.

Claims Rejected Under 35 U.S.C. Section 112, Second Paragraph

Claims 20-22, 49-54, 59-69, 96, 97, 100-105 and 282 were rejected under 35 U.S.C. Section 112, second paragraph, as being indefinite. Regarding claims 20-22, 49-54, 59-69, 96, 97 and 100-105, the Examiner indicated that the phrase “the step of providing...” lacks antecedent basis. In response thereto, Applicants have amended these claims above to delete the phrase “the step of providing”. Claim 96 has been canceled above, without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

With regard to claim 282, “the flexible tubular member” has been changed to –the malleable tubular member--.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 20-22, 49-54, 59-69, 96, 97, 100-105 and 282 under 35 U.S.C. Section 112, second paragraph, as being no longer appropriate.

Claim Rejected Under 35 U.S.C. Section 102(b) (Costello et al.)

Claim 106 was rejected under 35 U.S.C. Section 102(b) as being clearly anticipated by Costello et al., U.S. Patent No. 5,593,404. In view of the above amendment of claim 106, it is respectfully submitted that Costello et al. clearly fails to disclose each and every feature recited in claim 106. Costello et al. provides a method of treating a patient’s prostate, in which a laterally transmitting laser fiber tip of a laser fiber is placed in an endoscopic instrument adjacent to a window opening 30 formed in a distal end portion of the instrument. Laser light energy is transmitted from the tip, through the

opening on to the interior wall of the prostatic urethra.

Claim 106 has been amended above to recite that the distal end portion of the guide catheter is devoid of openings through the wall of the catheter. Support for this amendment can be found, for example, at page 13, line 27 – page 14, line 2; page 21, lines 1-3 and Figs. 4A, 4B, 8, 9 and 16 of the specification.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claim 106 under 35 U.S.C. Section 102(b) as being clearly anticipated by Costello et al., U.S. Patent No. 5,593,404, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 102(b) (Bednarek)

Claims 106 and 107 were rejected under 35 U.S.C. Section 102(b) as being clearly anticipated by Bednarek [et al.], U.S. Patent No. 5,785,706. In view of the above amendments of claim 106 and 107, it is respectfully submitted that Bednarek clearly fails to disclose each and every feature recited therein. Bednarek provides a guiding introducer containing openings. An ablation catheter is inserted through the guiding introducer and an electrode contained at the distal end of the catheter is at least partially aligned with at least one opening to contact the cardiac tissue with sufficient pressure to create a lesion.

Claims 106 and 107 have been amended above to recite that the distal end portion of the guide catheter is devoid of openings through the wall of the catheter. Support for this amendment can be found, for example, at page 13, line 27 – page 14, line 2; page 21, lines 1-3 and Figs. 4A, 4B, 8, 9 and 16 of the specification.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 106 and 107 under 35 U.S.C. Section 102(b) as being clearly anticipated by Bednarek, U.S. Patent No. 5,785,706, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 102(e) (Sinofsky et al.)

Claims 225, 240, 243, 246, 248-249, 253, 293-295 and 297 were rejected under 35 U.S.C. Section 102(e) as being clearly anticipated by Sinofsky et al., U.S. Patent No. 6,558,375. The Examiner referred to Figs. 1-7 and column 8, line 34 to column 4, line 25. In view of the above amendment and following remarks, Applicants respectfully traverse this ground of rejection.

Initially, Applicants note that Sinofsky et al., U.S. Patent No. 6,558,275 does not appear to have

a column 8, and the Examiner's reference thereto appears to be a typographical error.

Sinofsky et al. discloses a hand held cardiac ablation instrument that includes a circumferential ablation element 12, and a handle 14 for manual placement of the element 12 in contact with a targeted tissue area. A light transmitting optical fiber 18 and a light diffusing element 32 including a scattering medium 28 make up the element 12. Thus, when light is emitted axially from the distal end of the optical fiber 18, light is dispersed by the scattering particles 22, reflected by the reflective end 24 and scattered again. The device is a handheld cardiac ablation instrument, see Fig. 1. The ablation element 12 is contacted to an tissue surface to be ablated, and the instrument is actuated to effect the ablation. No sheath, guide or catheter is provided to guide delivery and placement of the ablation element 12. Although Sinofsky et al. discloses an embodiment in which the light transmitting optical fiber 18A can slide within housing 26, this is only an adjustment feature, and the optical fiber 18A is still contained within the housing 26 as an integral part of the instrument 10.

Claim 225 has been amended above to recite a step of inserting the ablative device through the at least one lumen of the ablation sheath. It is respectfully submitted that Sinofsky et al. does not disclose or suggest this step since the device 10 is an integral handheld device and the ablation element 12 is not inserted through an ablation sheath. Further, the fiber 18 and housing 26 are advanced against the tissue as a unit.

With regard to claims 293 and 297, it is respectfully submitted that Sinofsky et al. fails to disclose the step of maintaining alignment of the ablation means or device and the at least one lumen relative to a rotational direction about a longitudinal axis of the at least one lumen during transluminally positioning steps. Sinofsky et al. discloses that light transmitted into the housing 26 is scattered in a circular pattern along the length of the ablation element. Accordingly, Sinofsky et al. teaches against maintaining rotational alignment, since rotational alignment is not necessary. Rotational alignment is not necessary with the device of Sinofsky et al. because light is scattered in a circular pattern. Accordingly, the rotational orientation of the light fiber 18 relative to the housing 26 is inconsequential. Referring to Fig. 4, Sinofsky et al. discloses that the light transmitted into the housing is scattered in a circular pattern. It is respectfully submitted that this suggests that the housing has a circular cross-section. In any case, it is respectfully submitted that Sinofsky et al. does not teach maintaining rotational alignment of the light fiber 18 with the housing 26, as this is completely unnecessary in the device of Sinofsky et al.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 225, 240, 243, 246, 248-249, 253, 293-295 and 297

under 35 U.S.C. Section 102(e) as being clearly anticipated by Sinofsky et al., U.S. Patent No. 6,558,375, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103 (Bednarek in combination with Sinofsky et al.)

Claims 1, 5, 9-11, 14-16, 25-33, 40-54, 58-69, 71-72, 86-87, 89-91, 96-97, 100-105, 296, 298 and 299 were rejected under 35 U.S.C. Section 103 as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375. The Examiner asserted that Bednarek teaches a method as claimed except for maintaining rotational alignment. The Examiner further asserted that Sinofsky et al. teaches a cardiac ablation device employing a slidably positionable ablation element with a rotationally asymmetric cross section positioned in sheath in an lumen with a complimentary shape wherein the energy can be directionalized. The Examiner asserted that it would have been obvious to employ the rotationally asymmetric cross section lumen and ablative element of Sinofsky et al. in the method of Bednarek, since this would enable less energy to be used in the procedure, since more of it would be directed towards the tissue.

Applicants respectfully traverse. Applicants respectfully submit that neither Sinofsky et al., nor Bednarek, discloses or suggests maintaining alignment of the ablative device and the at least one lumen relative to a rotational direction about a longitudinal axis of the at least one lumen during transluminally slidably positioning steps. Sinofsky et al. discloses that light transmitted into the housing 26 is scattered in a circular pattern along the length of the ablation element. Accordingly, Sinofsky et al. teaches against maintaining rotational alignment, since rotational alignment is not necessary. Rotational alignment is not necessary with the device of Sinofsky et al. because light is scattered in a circular pattern. Accordingly, the rotational orientation of the light fiber 18 relative to the housing 26 is inconsequential.

The Examiner asserted that Sinofsky et al. teaches an ablation element with a rotationally asymmetric cross section position in a sheath in a lumen with a complimentary shape. Referring to Fig. 4, Sinofsky et al. discloses that the light transmitted into the housing is scattered in a circular pattern. It is respectfully submitted that this suggests that the housing has a circular cross-section, not a rotationally asymmetric cross-section as asserted by the Examiner. It is further respectfully submitted that Applicants were unable to locate a description of a rotationally asymmetric cross section by Sinofsky et al. In any case, it is respectfully submitted that Sinofsky et al. does not teach maintaining rotational alignment of the light fiber 18 with the housing 26, as this is completely unnecessary in the device of

Sinofsky et al.

Accordingly, Applicants respectfully submit that the presently rejected claims would not have been obvious over Bednarek and Sinofsky et al., and that the Examiner has relied upon improper hindsight, gained from a reading of the present specification, to provide a teaching for maintaining rotational alignment.

In view of the above remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5, 9-11, 14-16, 25-33, 40-54, 58-69, 71-72, 86-87, 89-91, 97, 100-105, 296, 298 and 299 (claim 96 having been canceled without prejudice) under 35 U.S.C. Section 103 as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Bednarek in combination with Sinofsky et al. and Cox et al.)

Claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, as applied to claims 1, 5, 9-11, 14-16, 25-33, 40-54, 58-69, 71-72, 86-87, 89-91, 96-97, 100-105, 296, 298 and 299 above, and further in combination with Cox et al., WO 98/17187 and “the admitted prior art of including a cutting member on the distal end of the sheath, since this would allow the cut to be made without introducing an additional tool, thus simplifying the procedure, as simplification is desirable; employing a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; and to apply energy to assure that the ablation has been effective; and performing a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures”. The Examiner asserted, regarding the response filed January 29, 2007, that Applicants did not challenge the Examiner’s official notice of various “facts” and that thus these officially noticed facts are taken to be admitted prior art. The Examiner referred to MPEP 2144.03(C) as support for his assertion.

Applicants respectfully traverse the Examiner’s assertions. Applicants note that on page 3 of the Official Action of September 28, 2006, the Examiner took official notice that simplification of a

procedure is desirable. The Examiner is correct that Applicants did not dispute the Examiner statement regarding simplification being desirable. However, the Examiner's statement that it would have been obvious to include a cutting member on the distal end of the sheath is not a statement of purported "fact", but is a statement asserting that it would have been obvious to modify a reference. It is respectfully submitted that such a statement is not appropriately supported by "official notice". The MPEP section that the Examiner referred to (MPEP 2144.03(c)) states that "Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." This same section further states "the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961))." It is respectfully submitted that it is at least arguable whether or not it would have been obvious to modify the sheath (the Examiner was not clear as to which reference the sheath to be modified is disclosed in) with a cutting member on the distal end thereof, as suggested by the Examiner. For this reason, it is respectfully submitted that the Examiner's statement of obviousness is not supported by simply asserting "official notice". Applicants respectfully submit that a question of obviousness cannot generally be supported as a statement of "fact". Accordingly, it is respectfully submitted that the application of "official notice" as a sole means of establishing a *prima facie* case of obviousness is generally improper, as application of official notice is to be limited to facts and statements of obviousness are not statements of facts.

Likewise, it is respectfully submitted that the Examiner's assertion that it would have been obvious to employ a key to enable the surgeon to recognize the orientation of the surgical device is not a statement of fact, is disputable, and is therefore not the proper subject for an assertion of official notice. This is also a question of obviousness, and therefore the proper requirements must be met to establish a *prima facie* case of obviousness. The Examiner's statement is so vague that Applicants were unable to determine which specific claim or claims that this statement of obviousness were purported to have been applied. Claim 51 recites providing the flexible tubular member with a key assembly to properly align the energy delivery portion within the distal end portion of the flexible tubular member for aligning the predetermined direction of the ablative energy with the tissue region to be ablated. However, the Examiner's statement of "official notice" mentions neither a flexible tubular member, or aligning a predetermined direction of ablative energy, but only takes official notice that a key is a notorious orientation indicator. Applicants would disagree, since it is much simpler to simply place a mark on a

device to indicate its orientation, and the Examiner has already established by official notice that simplification of a procedure is desirable. In any case, the Examiner has not set forth a *prima facie* case of obviousness regarding providing a key assembly to properly align the energy delivery portion within the distal end portion of the flexible tubular member.

The Examiner further took “official notice” that it would have been obvious to sense the temperature, since this is notorious for ablating in sensitive organs such as the heart. Once again, this is a statement of obviousness, which Applicants respectfully submit is not capable of instant and unquestionable demonstration that defies dispute, and therefore is not properly supported solely on the basis of “official notice”. Further, it is not clear as to which claim or claims are intended to be rejected based on the Examiner’s statement, since the statement was only that it would have been obvious to sense the temperature. Claim 78 recites that the distal end portion of the flexible tubular member includes at least one temperature sensor, and that the method further comprises measuring a temperature of the tissue region using the temperature sensor. The Examiner did not assert that it would have been obvious to provide a flexible tubular member including at least one temperature sensor, or that it would have been obvious to measure a temperature of the tissue region using the temperature sensor. The Examiner merely asserted, by “official notice”, that it would be obvious to sense the temperature. Temperature sensing can be performed by many different methods and many different devices or mechanisms. Accordingly, it is respectfully submitted that the Examiner has not set forth a *prima facie* case of obviousness with respect to claims 78 and 79. Although the Examiner may attempt to take official notice as to the act of sensing temperature, it is respectfully submitted that such official notice did not specifically apply to the specific sensing methods recited in claims 78 and 79.

The Examiner further took “official notice” that it would have been obvious to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart. Although the Examiner may attempt to take “official notice” of a “fact”, such as “sensing between the device and tissue to be ablated is known”, it is respectfully submitted that the Examiner’s assertion that it would have been obvious to sense contact between the device (of one of the references) and the tissue to be ablated, is not a statement of fact and is open to dispute. Accordingly, it is respectfully submitted that official notice has been improperly applied here. Further, it is not clear which claim or claims the Examiner intended to reject with this statement of obviousness. Claim 70 recites a flexible member having one or more electrodes coupled to said distal end portion of the flexible tubular member, said method further comprising: sensing contact between the flexible tubular member and the tissue region to be ablated using said one or more electrodes. However, the Examiner has not

set forth a *prima facie* case of obviousness as to providing one or more electrodes to the distal end of a flexible member and sensing contact between the flexible tubular member and a tissue region to be ablated using the one or more electrodes. Rather, the Examiner has simply stated that it would have been obvious to sense contact between “the device” and the tissue to be ablated. The Examiner is not clear as to what is considered to constitute “the device”. The Examiner did not clearly indicate which reference is purported to be modified to perform the contact sensing. The Examiner did not indicate how contact would be sensed. Contact can be sensed by many different methods, including visually sensing. Accordingly, it is respectfully submitted that the Examiner improperly applied official notice to support a statement of obviousness regarding sensing contact. It is further respectfully submitted that the Examiner has failed to set forth a *prima facie* case of obviousness with regard to claim 70.

The Examiner took official notice that it would have been obvious to apply energy to assure that the ablation has been effective. It is respectfully submitted that it is improper to take official notice of this statement of obviousness, for reasons already noted above. Further, it is not clear which claim or claims this statement was applied to. It is respectfully submitted that none of the claims rejected under this ground of rejection recite “apply energy to assure that the ablation has been effective”. Accordingly, the Examiner is specifically requested to clarify which claims, if any, this statement of obviousness is intended to reject.

The Examiner asserted that it would have been obvious to the artisan of ordinary skill in the art to employ the maze procedure and ablation means of Cox et al. in the combined method of Bednarek in combination with Sinofsky et al., or to employ the particular ablation steps of the combined teachings of Bednarek in combination with Sinofsky et al in the method of Cox et al., since Cox et al teach nor particular form for the cryogenic ablation elements, to employ the cryogenic directional ablation element features claimed since these are merely a matter of choice and provides no unexpected result and are known means for providing the desirable functions of Cox et al. Applicants respectfully traverse. It is respectfully submitted that it is improper to combine the directional ablation features of the present invention with the disclosure of Cox et al. in an effort to meet the limitations of the present claims. It is respectfully submitted that it is further improper to simply dismiss the specific features claimed as “a matter of choice” and “known means”. The Examiner is respectfully requested to supply at least one reference that supports the Examiner’s conclusions, as well as to meet the other requirements for establishing a *prima facie* case of obviousness.

Further, it is respectfully submitted that none of the references applied discloses, teaches or suggests “maintaining alignment of the ablative device and the at least one lumen relative to a rotational

direction about a longitudinal axis of the at least one lumen, during said transluminally slidably positioning steps, by a cooperative configuration of the ablation means and the at least one lumen" as recited in claim 1 and recited in similar fashion in claims 293 ad 297. For this additional reason, it is respectfully submitted that this ground of rejection is inappropriate.

With respect to claim 282, it is respectfully submitted that Cox et al. does not teach the providing of a malleable tubular member through which at least one ablation element is transluminally slid.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, as applied to claims 1, 5, 9-11, 14-16, 25-33, 40-54, 58-69, 71-72, 86-87, 89-91, 96-97, 100-105, 296, 298 and 299 above, and further in combination with Cox et al., WO 98/17187, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Bednarek in combination with Sinofsky et al., Cox et al. and Swanson et al.)

Claims 70-79 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in combination with Swanson et al., U.S. Patent No. 6,076,012. The Examiner asserted that Swanson et al. teaches using temperature sensors to control ablation and electrodes to pace, map, etc., the heart in a maze procedure wherein the pulmonary vein is encircled. The Examiner asserted that it would have been obvious to employ the sensors and the pulmonary vein encircling device in the combined method of Bednarek, Sinofsky et al. and Cox et al. since this would enable the performance of beneficial cardiac procedures, such as maze or to employ the longitudinally translatable ablation element of the combined method of Bednarek, Sinofsky et al. and Cox et al. in the method of Swanson et al. since this can create longer lesions with a single ablation element.

Applicants respectfully traverse. Claims 70-79 depend from claim 1 and it is respectfully submitted that none of the applied references teaches or discloses maintaining alignment of the ablative device and the at least one lumen relative to a rotational direction about a longitudinal axis of the at least

one lumen, during said transluminally slidably positioning steps, by a cooperative configuration of the ablation means and the at least one lumen. Swanson contributes nothing to overcome this defect.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 70-79 under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in combination with Swanson et al., U.S. Patent No. 6,076,012, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Bednarek in combination with Sinofsky et al., Cox et al. and Kesten et al.)

Claims 90-91 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in view of Kesten et al., WO 96/35469. The Examiner asserted that Kesten et al. teaches delivering ablation devices with a pre-shaped sleeve to reach the ventricles via the peripheral veins, and that it would have been obvious to employ the sheath, delivering route and treatment region of Kesten et al. in the combined method of Bednarek et al., Sinofsky et al. and Cox et al., or to employ the directional slidable probe in a sheath of the combined method of Bednarek, Sinofsky et al, Cox et al. and Kesten et al., since this would allow the treatment of an elongated area without repositioning the device, and in either case, to treat one of the atria or ventricles.

Applicants respectfully traverse. Applicants respectfully submit that claims 80-91 depend from claim 1 and it is respectfully submitted that none of the applied references teaches or discloses maintaining alignment of the ablative device and the at least one lumen relative to a rotational direction about a longitudinal axis of the at least one lumen, during said transluminally slidably positioning steps, by a cooperative configuration of the ablation means and the at least one lumen, as Kesten et al. does not deliver ablative energy through an ablation sheath or tubular member, but extends the therapeutic device 3 distally out of the open end of the delivery catheter to apply therapy.

In view of the above amendments and remarks, the Examiner is respectfully requested to

reconsider and withdraw the rejection of claims 80-91 under 35 U.S.C. Section 103(a) as being unpatentable over Bednarek [et al.], U.S. Patent No. 5,785,706 in combination with Sinofsky et al., U.S. Patent No. 6,558,375, and Cox et al., WO 98/17187, as applied to claims 5-8, 12-13, 17-22, 25-33, 40-42, 46-54, 58-72, 78-79, 105, 225, 229-242, 244-245, 247, 250-252, 254-255, 282, 284-292 and 300 above, and further in view of Kesten et al., WO 96/35469, as being inappropriate.

Claims Rejected Under the Judicially Created Doctrine of Obviousness-Type Double Patenting (U.S. Patent No. 7,033,352)

Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,033,352. It is respectfully submitted that a terminal disclaimer was submitted in the previous response, filed January 29, 2007, together with a Power of Attorney establishing the undersigned as an attorney of record.

Accordingly, in view of the above remarks, it is respectfully submitted that this ground of rejection is improper and should be withdrawn. The Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 (sic, 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300) under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 7,033,352, as being clearly inappropriate.

Claims Rejected Under the Judicially Created Doctrine of Obviousness-Type Double Patenting (U.S. Patent No. 6,962,586)

Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,962,586. It is respectfully submitted that a terminal disclaimer was submitted in the previous response, filed January 29, 2007, together with a Power of Attorney establishing the undersigned as an attorney of record.

Accordingly, in view of the above remarks, it is respectfully submitted that this ground of rejection is improper and should be withdrawn. The Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282

and 284-300 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,962,586, as being clearly inappropriate.

Claims Rejected Under the Judicially Created Doctrine of Obviousness-Type Double Patenting (U.S. Patent No. 6,673,068)

Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-13, 19-64 and 68 of U.S. Patent No. 6,673,068. It is respectfully submitted that a terminal disclaimer was submitted in the previous response, filed January 29, 2007, together with a Power of Attorney establishing the undersigned as an attorney of record.

Accordingly, in view of the above remarks, it is respectfully submitted that this ground of rejection is improper and should be withdrawn. The Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-13, 19-64 and 68 of U.S. Patent No. 6,673,068, as being clearly inappropriate.

Claims Rejected Under the Judicially Created Doctrine of Obviousness-Type Double Patenting (U.S. Patent No. 6,312,427)

Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,312,427. It is respectfully submitted that a terminal disclaimer was submitted in the previous response, filed January 29, 2007, together with a Power of Attorney establishing the undersigned as an attorney of record.

Accordingly, in view of the above remarks, it is respectfully submitted that this ground of rejection is improper and should be withdrawn. The Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 under the judicially created doctrine of obviousness-type double patenting as being

unpatentable claims 1-29 of U.S. Patent No. 6,312,427, as being clearly inappropriate.

Claims Rejected Under the Judicially Created Doctrine of Obviousness-Type Double Patenting (U.S. Patent No. 6,245,062)

Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-13, 15-16 and 18-19 of U.S. Patent No. 6,245,062. It is respectfully submitted that a terminal disclaimer was submitted in the previous response, filed January 29, 2007, together with a Power of Attorney establishing the undersigned as an attorney of record.

Accordingly, in view of the above remarks, it is respectfully submitted that this ground of rejection is improper and should be withdrawn. The Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 under the judicially created doctrine of obviousness-type double patenting as being unpatentable claims 12-13, 15-16 and 18-19 of U.S. Patent No. 6,245,062, as being clearly inappropriate.

Claims Provisionally Rejected Under the Judicially Created Doctrine of Obviousness-Type Double Patenting (U.S. Patent Application No. 10/211,685)

Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 22, 43, 47-49, 53-54, 97 and 116 of U.S. Patent Application No. 10/211,685. It is respectfully submitted that a terminal disclaimer was submitted in the previous response, filed January 29, 2007, together with a Power of Attorney establishing the undersigned as an attorney of record.

Accordingly, in view of the above remarks, it is respectfully submitted that this ground of rejection is improper and should be withdrawn. The Examiner is respectfully requested to reconsider and withdraw the provisional rejection of claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 22, 43, 47-49, 53-54, 97 and 116 of U.S. Patent Application No.

10/211,685., as being clearly inappropriate.

Claims Provisionally Rejected Under the Judicially Created Doctrine of Obviousness-Type Double Patenting (U.S. Patent Application No. 10/253,737)

Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8 and 14-17 of U.S. Patent Application No. 10/253,737. It is respectfully submitted that a terminal disclaimer was submitted in the previous response, filed January 29, 2007, together with a Power of Attorney establishing the undersigned as an attorney of record.

Accordingly, in view of the above remarks, it is respectfully submitted that this ground of rejection is improper and should be withdrawn. The Examiner is respectfully requested to reconsider and withdraw the provisional rejection of claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 8 and 14-17 of U.S. Patent Application No. 10/253,737, as being clearly inappropriate.

Claims Provisionally Rejected Under the Judicially Created Doctrine of Obviousness-Type Double Patenting (U.S. Patent Application No. 10/348,256)

Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 15-42 of U.S. Patent Application No. 10/348,256. It is respectfully submitted that a terminal disclaimer was submitted in the previous response, filed January 29, 2007, together with a Power of Attorney establishing the undersigned as an attorney of record.

Accordingly, in view of the above remarks, it is respectfully submitted that this ground of rejection is improper and should be withdrawn. The Examiner is respectfully requested to reconsider and withdraw the provisional rejection of claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 15-42 of U.S. Patent Application No. 10/348,256, as being clearly inappropriate.

Claims Provisionally Rejected Under the Judicially Created Doctrine of Obviousness-Type Double Patenting (U.S. Patent Application No. 10/897,232)

Claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent Application No. 10/897,232. It is respectfully submitted that a terminal disclaimer was submitted in the previous response, filed January 29, 2007, together with a Power of Attorney establishing the undersigned as an attorney of record.

Accordingly, in view of the above remarks, it is respectfully submitted that this ground of rejection is improper and should be withdrawn. The Examiner is respectfully requested to reconsider and withdraw the provisional rejection of claims 1, 5-22, 25-33, 40-54, 58-91, 96-97, 100-107, 225, 229-255, 282 and 284-300 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-72 of U.S. Patent Application No. 10/897,232, as being clearly inappropriate.

Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

Atty Dkt. No.: GUID-117 (formerly FMT1P028)

USSN: 09/751,472

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-117.

Respectfully submitted,

LAW OFFICE OF ALAN W. CANNON

Date: 5/2/07

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